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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/495,556	02/01/2000	Eric H. Kuhrts		5012

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EXAMINER	
DI NOLA BARON; LILIANA	
ART UNIT	**PAPER NUMBER**
1615	28

DATE MAILED: 11/04/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/495,556	KUHRTS, ERIC H.	
	Examiner	Art Unit	
	Liliana Di Nola-Baron	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 September 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *51-94,96-98,101-105 and 107* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *51-94,96-98,101-105 and 107* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Receipt of Applicant's amendment, filed on September 22, 2003, is acknowledged.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claims 51-93 are rejected under 35 U.S.C. 103(a) as being unpatentable over Steber et al. (U.S. Patent 4,837,381).

Steber et al. provides a method for the preparation of microspheres (See Example 1) and discloses microsphere compositions comprising a fat or a wax having melting points higher than 40°C (104 Deg. F.) or mixtures thereof and a biologically active protein, peptide or polypeptide, including growth hormone and growth factors (See col. 2, lines 15-59). Steber et al. includes vegetable waxes, and specifically sugar cane (which contains 15-20% of sucrose), and mineral waxes among the waxes used in the invention (See col. 2, lines 60-68). Thus, the compositions disclosed by Steber et al. comprise a core material mixed with an oil and further comprising a sugar and/or a mineral. Steber et al. teaches that the microspheres of the invention are dispersed in animal or vegetable oil and metal compounds may be added to the compositions (See col. 3, lines 28-54 and col. 4, lines 28-46). Specifically, Steber et al. includes soybean oil among the vegetable oils

used in the invention (See col. 5, lines 21-31). Steber et al. provides a process for preparing the microspheres of the invention, said process comprising mixing the active ingredient with the fat, wax or mixtures thereof, forming microspheres and cooling (See col. 5, lines 32-50). The preparation of microspheres in Example 1, #2, is performed by mixing the active ingredient with the fat, wax or mixtures thereof, spraying the mixture through a spray nozzle equipped with a heated jacket and cooling the formed microspheres. Thus, the process disclosed by Steber et al. comprises adding a core material and an oil into a mixer, mixing them until microencapsulated particles are formed and discharging the particles, as claimed in claims 51-57, 61, 63, 65-72, 76 and 78 of the instant application. Regarding claims 80-93, the patent is deficient in the fact, that it does not specifically disclose the speed used in the mixer, however, one of ordinary skill in the art would have determined the optimal speed by routine experimentation. With respect to Applicant proviso that no classification step is performed during the microencapsulation process, Example 1, #2 in Steber et al. teaches that collection of the microspheres on a series of sieves is done only after the microencapsulation process is completed, thus no classification step is performed during the microencapsulation process. With respect to the amount of oil claimed in the instant application (claims 58-60, 73-75 and 87-89), claim 17 in the patent discloses a composition obtained by heating 1-30% of growth hormone and 5-60% of fat or wax or mixtures thereof, dispersing said mixture in oil and cooling the composition. With respect to the amounts of sugar and mineral in the composition and process claimed in the instant application (claims 62, 64, 77, 79, 91 and 93), the patent is silent regarding the amounts of sugar cane and mineral wax used in the invention, however, one of ordinary skill in the

art would have been able to determine the optimal concentration range by routine experimentation.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to apply the teachings of Steber et al. to device processes for the encapsulation of biological material. The expected result would have been a successful process for the encapsulation of active agents. Because of the teachings of Steber et al., that the process of the invention is successful in forming compositions for the controlled release of drugs, one of ordinary skill in the art would have a reasonable expectation that the processes claimed in the instant application would be successful at forming microencapsulated drugs. Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

3. Claims 51-94, 96-98, 101-105 and 107 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cuca et al. (U.S. Patent 5,494,681).

Cuca et al. provides a delivery system comprising an active material and a wax having a melting point between 50° and 200°C (122 and 392 Deg. F), and a process for preparing said system (See col. 2, lines 31-59).

With regard to instant claims 51-93, the method disclosed by Cuca et al. includes melting the wax, adding the active material to the matrix comprising the wax and solidifying the

mixture to form particles while spin congealing, wherein a high speed mixer is used (See col. 6, lines 17-30). The patent does not specifically disclose microcapsules or microencapsulation process, however it contemplates the formation of particles. Thus, in the method disclosed by Cuca et al. the particles are formed while the ingredients are mixed, no classification step is performed during the microencapsulation process and the method comprises the step of cooling the particles, as claimed by Applicant. With respect to claims 80-93, the patent does not specifically disclose the speed used in the high speed mixer, however, one of ordinary skill in the art would have determined the optimal speed by routine experimentation. With regard to claims 94, 96-98, 101-105 and 107, Cuca et al. discloses particles for oral administration comprising a drug encapsulated within a matrix comprising a wax for the control of the bioavailability of the drug (See col. 2, lines 25-46). The matrix disclosed by Cuca et al. also contains a hydrophobic polymer (See col. 2, lines 39-46). The examiner relates to the "consisting essentially of" language in instant claim 94 as possibly including additional ingredients that are not detrimental to the claimed composition and do not alter the characteristics of the claimed composition. In fact, dependent claim 102 in Applicant's application is directed to the composition of claim 94 further comprising a sugar or a mineral. Thus, the compositions claimed by Applicant allow for the presence of additional ingredients, such as the hydrophobic polymer disclosed by the prior art. Cuca et al. includes a great variety of active agents, which can be delivered by the system of the invention (See col. 3, line 7 to col. 4, line 14), and teaches that the amount of wax, including animal and vegetable waxes, is 10-95% (See col. 3, lines 30-47), and the amount of excipients, including sweeteners and pH modifiers, is 0.01 –75% (See col. 5, lines 3-10). Specifically, Cuca et al. includes sucrose,

dextrose and maltose among the sugars used in the invention and teaches that the excipients may be added to the matrix anytime during processing (See col. 7, lines 17-50). With respect to claim 66, Cuca et al. does not specifically disclose the use of a screw auger, however, one of ordinary skill in the art would have been capable of selecting the most suitable equipment for the method of the invention. With respect to the iodine value claimed in claim 107, the patent is silent about the iodine value of the oils used in the invention, however, it contemplates using vegetable wax (See col. 4, lines 43-47), and one of ordinary skill in the art would have been able to determine the optimal iodine value by routine experimentation.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to apply the teachings of Cuca et al. to device a process for the encapsulation of biological material and particles comprising an active agent for oral administration of said agent in a controlled manner. The expected result would have been a successful process for the encapsulation of active agents and successful compositions comprising active agents. Because of the teachings of Cuca et al., that the process of the invention is successful in forming compositions for the controlled bioavailability of drugs in oral formulations, one of ordinary skill in the art would have a reasonable expectation that the processes and compositions claimed in the instant application would be successful at forming microencapsulated drugs. Therefore the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

4. Applicant's arguments, filed on August 11, 2003, have been fully considered, but they are not persuasive.

5. Applicant argues that the particles disclosed by Steber et al. are not formed during the mixing stage and the microspheres form while cooling on the sieves, with the mixture being homogeneous. In response to said argument, it is noted that in claim 54 of the instant application Applicant claims that the mixer comprises a heated jacket. Steber et al. teaches that the mixture is sprayed through an air/liquid spray nozzle equipped with a heated jacket and the microspheres are formed as the molten droplets cool (See col. 6, lines 8-15). Thus, the microspheres disclosed by Steber et al. are formed in the heated jacket of the mixer, as claimed by Applicant.

Conclusion

6. Claims 51-94, 96-98, 101-105 and 107 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Liliana Di Nola-Baron whose telephone number is 703-308-8318. The examiner can normally be reached on Monday through Thursday, 5:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 308-1234/ 1235.

October 31, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600